REMARKS/ARGUMENTS

Claims 1 and 4-10 are pending in the application.

Claim 1 has been amended to more clearly recite that the method of treating an Alzheimer's patient comprises administering a daily dosage consisting essentially of from 100 mg to less than 1,000 mg of hypoxanthine, xanthine and/or inosine to the patient.

Claims 1 and 4-10 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Laruelle et al. '387 in view of Sandyk '846 and further in view of Castillo et al. '994. According to the Office Action, Laruelle et al. '387 discloses a pharmaceutical composition suitable for increasing cerebral serotonin concentration comprising a serotonin precursor and inosine and hypoxanthine. The Office Action states that treatment consists of administering to a mammal having a lower than normal cerebral serotonin level an amount of a pharmaceutical composition as presently claimed effective to increase the cerebral serotonin level, with daily dosages to 1 to 100 mg/kg being preferred. Sandyk '846 is relied upon as teaching a method of treating neurological and mental disorders which are associated with and/or related pathogenetically to deficient serotonin neurotransmission, with Alzheimer's disease being a disorder associated with deficient levels of serotonin. Castillo et al. '994 is relied upon as teaching herbal compositions for intervention in Alzheimer's disease which may optionally include antioxidants. It is submitted that the present invention, as recited in amended Claim 1, is patentable over the prior art of record.

Laruelle et al. '387 discloses pharmaceutical compositions based upon 5-hydroxytryptophan (5-HTP) and derivatives of 5-hydroxytryptophan, in combination with a nitrogenous heterocyclic compound selected from a group that includes inosine and hypoxanthine (see abstract and column 1, line 60 to column 2, line 16). According to Laruelle et al. '387, the combination of 5-HTP and derivatives of purine, pyrimidine or pyridine bases provide novel pharmaceutical compositions capable of correcting deficiencies of serotonin metabolism:

> The present invention provides novel pharmaceutical compositions capable of correcting the deficiencies of serotonin metabolism which are characterized in that they comprise an association of 5-HTP or a derivative

> thereof with derivatives of purine, pyrimidine, or pyridine bases, or with a combination of derivatives of these bases.
>
> The applicants have in fact observed that the combination of 5-HTP with a purine, pyridine, or pyrimidine heterocyclic base enables the cerebral levels of 5-HTP, serotonin and 5-hydroxyindolacetic acid (5-HIAA), which is the principal metabolite of serotonin, to be considerably increased. (column 3, lines 17-29)

The disclosed pharmaceutical composition must have at least 5 percent 5-HTP that is chemically associated with the nitrogenous heterocyclic base (see column 3, lines 38-46). The 5-HTP-containing pharmaceutical compositions disclosed by Laruelle et al. '387 are said to triple blood levels of 5-HTP and 5-hydroxyindolacetic acid (5-HIAA), the principal metabolite of serotonin (column 4, lines 1-6). Laruelle et al. '387 discloses several specific examples of pharmaceutical compositions which were the subject of a pharmacological study. As set forth in columns 5-9, all of the studied compositions included significant amounts of 5-HTP.

It is clear from the teachings of Laruelle et al. '387 that 5-HTP must be present in significant amounts in the disclosed pharmaceutical compositions, and represents the primary active ingredient of the compositions when administered to patients. In contrast, the presently claimed method excludes the use of the levels of 5-HTP taught by Laruelle et al. '387 by reciting that the method comprises administering a daily dosage consisting essentially of from 100 mg to less than 1,000 mg of hypoxanthine, xanthine and/or inosine to a patient. The recited daily dosage consisting essentially of specified amounts of hypoxanthine, xanthine and/or inosine excludes additional ingredients that would affect the basic and novel characteristics of the claimed daily dosage. Laruelle et al. '387 teaches that 5-HTP is the primary active ingredient of the disclosed pharmaceutical compositions, and is required in order to effectively increase serotonin levels in patients. The presently claimed invention therefore distinguishes over the reference because the levels of 5-HTP required by Laruelle et al. '387 are excluded from the daily dosage recited in Claim 1.

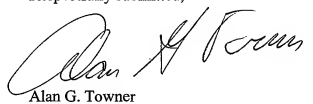
Sandyk '846 and Castillo et al. '994 do not remedy the above-noted deficiencies of Laruelle et al. '387. Even if the secondary references could properly be combined with Laruelle et al. '387 as suggested in the Office Action, such a combination would not read on the presently claimed method of treating an Alzheimer's patient by administering a daily dosage

consisting essentially of the recited amounts of hypoxanthine, xanthine and/or inosine to the patient. Accordingly, Claim 1, and Claims 4-10 which depend therefrom, are patentable over Laruelle et al. '387 alone, or in combination with Sandyk '846 and Castillo et al. '994.

In view of the foregoing amendments and remarks, it is submitted that Claims 1 and 4-10 are patentable over the prior art of record. Accordingly, an early Notice of Allowance of this application is respectfully requested.

In the event that any outstanding matters remain in connection with this application, the Examiner is invited to telephone the undersigned at (412) 263-4340 to discuss such matters.

Respectfully submitted,



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